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(71) Applicant: TFX MEDICAL EXTRUSION PRODUCTS [US/US]; 3750 Annapolis Lane North, Suite 160, Plymouth, MN 55447 (US).

(72) Inventors: ANDERSON, Brent; 5194 95th Street, S.E., Delano, MN 55328 (US). BERHOW, Steven; 9177 13th Street, N.E., St. Michael, MN 55376 (US).

(74) Agents: CONLIN, David, G. et al.; Dike, Bronstein, Roberts & Cushman LLP, 130 Water Street, Boston, MA 02109 (US).

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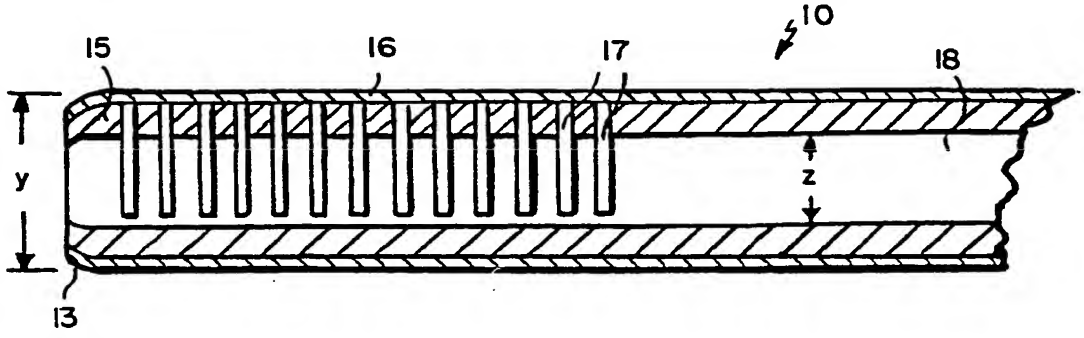
(54) Title: INTRODUCER DEVICE HAVING VARIABLE FLEXIBILITY AND KINK RESISTANCE AND METHOD OF MANUFACTURE OF SAME



(57) Abstract: The present invention relates to an improved introducer device for insertion of catheters and other devices into the vasculature of a patient. Introducer devices of the present invention incorporate a polymeric layer (16) jacketing a variably flexible sheath (10) having a proximal end (14), a distal end (13) and a longitudinal shaft (12) extending therebetween wherein the sheath (10) surrounds a reinforcement member (17) for kink resistance and a lubricious inner substrate (15) having an internal passageway (18). Methods for manufacture of such devices are also disclosed.

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INTRODUCER DEVICE HAVING VARIABLE FLEXIBILITY AND KINK-RESISTANCE AND METHOD OF MANUFACTURE OF SAME

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to an improved introducer device for insertion of catheters and other medical devices into a patient and methods of manufacture for such a device. Introducer devices of the present invention incorporate a variably flexible sheath surrounding a reinforcement member for kink resistance and a lubricious inner substrate.

2. Background

Various introducer devices have been developed for the insertion of catheters, guide wires and other medical devices into a patient. A typical procedure provides for insertion of a dilator or needle encased within a sheath into the vasculature of a patient. Following insertion, the dilator or needle may be removed leaving the sheath protruding from the vasculature of the patient. An ancillary medical device, e.g., a diagnostic or therapeutic catheter, is then threaded through the sheath into the patient.

A hub unit incorporating a hemostasis valve is typically attached to the sheath of the introducer at its proximal end in order to prevent uncontrolled bleeding and air embolism. The dilator or needle, and subsequently the ancillary medical device, pass through this hemostasis valve, the design of which is well known in the art.

In order to reduce trauma to the vasculature of the patient and the bleeding associated therewith that can be result from insertion of such devices, it is desirable to employ a sheath of minimal thickness, e.g., a thin-walled, reduced diameter sheath. It is also desirable to have some degree of flexibility with respect to the sheath. However, such a delicate construction inevitably can lead to kinking or bending of the

sheath. This is particularly problematic in emergency situations when time is of the essence. If the sheath becomes kinked or bent, a new introducer sheath must be inserted into the vasculature of the patient at the same or a different location.

Kinking and bending of the sheath may also occur in non-emergency situations. For example, certain procedures may require that the sheath remain within the vasculature of the patient for a prolonged period of time (e.g. 1-3 hours or more), e.g., during hemofiltration and dialysis procedures, various cardiovascular procedures and neurological surgical procedures. Certain procedures may require even longer residence times of the sheath within a patient, e.g. 24 hours or more.

Again, given the thin-walled, reduced diameter sheaths that are generally employed in devices of the prior art, mere movement of the patient can result in a compromise to the integrity of the sheath. It is difficult, if not impossible, to straighten a kinked or bent sheath. Therefore, once kinking or bending occurs, the sheath must be removed and the procedure restarted at a new site. This is especially troublesome in the case of patients who must undergo such procedures on a regular basis, as alternate sites for vascular access may be quite limited.

Certain devices incorporating tubular sheaths have been developed in an attempt to provide an introducer device that exhibits flexibility and kink-resistance, and presents minimal trauma to the vasculature of the patient.

More particularly, certain devices have been focused on the construction of the sheath itself. For example, U.S. Patent No. 5,066,285 (Hillstead) describes a catheter introducer sheath made of expanded fibrous polytetrafluoroethylene polymers and similar materials. That patent reports that the use such materials provides a highly flexible, non-kinking sheath.

The construction of certain other devices have focused on the tip of the introducer device. Specifically, several devices have incorporated a soft, distal tip construction in an effort to reduce trauma to the vasculature of the patient. For instance, in U.S. Patent No. 5,221,270 (Parker), a guiding catheter is reported having a soft tip for atraumatic insertion into coronary vessels that is suitable for introduction of an angioplasty balloon catheter. Similarly, U.S. Patent No. 5,234,416 (Macauley)

describes a guiding catheter having a non-traumatic distal tip which is reported as minimizing trauma to the arterial lining.

Such catheters with softer distal tip segments, however, present notable disadvantages. For example, a substantially weaker bond may necessarily exist between the soft tip and the less flexible, distal end of the catheter shaft. This is largely due to the thin catheter shaft walls (e.g., walls of less than 0.3 mm in thickness) and to the lower tensile strength of the softer tip materials.

Another sheath introducer device is described in U.S. Patent No. 5,700,253 (Parker). That patent reports a flexible, kink-resistant, introducer sheath suitable for percutaneous vascular access. In one embodiment, the introducer sheath includes a flat wire coil which is compression fitted about an inner polytetrafluoroethylene tube. Methods for the manufacture of the introducer sheath are also disclosed.

Despite the many advances in this field and the many devices currently available, there remains a need for an improved, kink-resistant introducer device that can facilitate smooth and non-traumatic entry of an ancillary medical device such as a catheter, guide wire or the like into a patient. Further, it would be highly desirable to develop a device with variable flexibility that avoids the difficulties observed with devices of the prior art having a soft, distal tip construction.

SUMMARY OF THE INVENTION

The invention provides improved introducer devices having flexibility and kink-resistance. In preferred aspects of the invention, the introducer device comprises a sheath that is capable of variable flexibility from proximal to distal end. Still more preferably, the introducer devices of the invention have a lubricious interior surface that provides for facile insertion of catheters and other devices through the introducer into a patient.

Introducer devices of the present invention generally comprise a sheath having a proximal end, a distal end and a longitudinal shaft, a lubricious inner substrate contained within the sheath, the lubricious inner substrate having an internal passageway adapted to receive a dilator, needle, catheter or other medical device, and a reinforcement member which is capable of surrounding the lubricious inner

substrate while being contained within the sheath. Preferably, the reinforcement material is not compression fit around the underlying sheath; instead, the reinforcement member has a larger inner diameter than the sheath outer diameter.

In preferred embodiments, introducer devices of the present invention further comprise a hub unit affixed to the proximal end of the sheath. The hub unit typically incorporates a valve for hemostasis which may or may not include a sideport for infusion or aspiration of fluids, a standard luer type hub or a custom hub suitable for interfacing with a specific catheter or other device.

The dilator is typically used in the placement of sheath introducers to dilate the opening in the tissue, to the sheath. Accordingly, in preferred embodiments of the present invention, the distal end of the sheath is tapered to provide a smooth transition between the dilator and sheath. This feature minimizes the force required to advance the dilator and sheath assembly through the skin and other tissues.

Typically, the outwardly exposed sheath is formed from a suitable polymer such as a polyurethane, polyethylene, polyester, nylon, nylon copolymer such as a polyetherblockamide (PEBA), and the like.

In preferred embodiments of the present invention, a polymeric layer jackets the outer surface of the sheath. In order to achieve variable flexibility of the sheath, the polymeric layer may comprise segments of different materials having different hardnesses. Alternately, the segments may comprise variations of the same material having different hardnesses. This particular feature enables one to readily alter the flexibility of the sheath and provides an introducer device that is easy to handle and maneuver, and that is non-traumatic to the vasculature of the patient.

In particularly preferred embodiments of the present invention, the distal end of the sheath is more flexible relative to the shaft portion of the sheath. This construction further provides for non-traumatic entry of the device into the vasculature of the patient.

Alternatively, the sheath may have substantially the same or a uniform flexiblity for the sheath length. Such a uniform flexibility will be more suitable for

relatively shorter sheathes, e.g. sheaths having an overall length of about 6 inches, 5 inches or 4 inches or less.

In accordance with the invention, the lubricious inner substrate provides a smooth surface for easy insertion and transverse movement of the dilator, and subsequently catheters and other ancillary medical devices within the sheath. Additionally, use of a smooth inner surface presents a surface which is resistant to blood clot formation.

In preferred aspects of the invention, the lubricious inner substrate comprises a fluoropolymer material. Particularly preferred fluoropolymers include polytetrafluoroethylene (PTFE) such as TEFLON, and fluorinated ethylene-propylene (FEP) polymers.

Alternatively, the lubricious inner substrate may be formed from a variety of flexible, non-reactive materials as long as the inside diameter of the substrate is substantially coated with a hydrophilic material. This particular embodiment is generally less preferred, however, due to cost and manufacturing difficulty associated with achieving uniform application of the hydrophilic coating on the inside surface of the substrate.

The reinforcement member reduces the possibility of kinking or bending of the sheath during and after entry into the vasculature of the patient. The reinforcement material is typically a coiled material, such a coiled metal, e.g. wound stainless steel braiding or a stainless steel spiral coil.

As discussed above, the reinforcement material preferably is not compression fit around the underlying sheath. Rather, the reinforcement member separate from the device has a larger inner diameter than the sheath outer diameter. Thus, for example, in a preferred design, an already wound coil reinforcement member is slid over a sheath member. The composite then may be suitably encapsulated at least in part by an outer layer, e.g. a polymer jacket.

The pitch of the braiding or coil may be varied in order to produce a reinforcement member with non-uniform spacing between the braiding or coil turns. Such pitching provides yet another way to vary the flexibility and relative strength of

the introducer sheath in order to tailor the introducer device to a particular use, procedure or access site, etc.

The sheath may further a detectable marker for monitoring the device within a patient, e.g. a radiopaque tracer ring, preferably positioned at the distal tip of the sheath. Such a configuration permits visualization of the distal end of the sheath within a patient by x-ray or fluoroscopic procedures.

Methods of manufacturing also are provided to produce introducer devices having flexibility and kink-resistance and incorporating a lubricious inner substrate. In preferred aspects, such methods generally include the steps of providing a sheath having a proximal end, a distal end, and a longitudinal shaft; providing a lubricious inner substrate having an internal passageway adapted to receive a dilator, needle or catheter, the lubricious inner substrate having a lesser diameter than the sheath; surrounding the lubricious inner substrate with a reinforcement member having a greater diameter than the lubricious inner substrate, but a lesser diameter than the sheath; inserting the lubricious inner substrate surrounded by the reinforcement member into the sheath; and molding the sheath to the lubricious inner substrate and reinforcement member.

Molding the sheath to the lubricious inner substrate and reinforcement member is preferably accomplished via a thermal fusion process. Using such a process, the sheath is extruded to provide the distal portion which may be tapered if desirable, and the hub unit can be molded directly onto the proximal end.

The hub unit also can be separately formed and then attached, such as by a suitable adhesive. Preferably however, the hub unit is insert molded to the sheath.

Other aspects of the invention are disclosed *infra*.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of an introducer device of the present invention.

FIG. 2 is an enlarged, partially sectioned view of the introducer device shown in FIG. 1.

FIG. 3 depicts the introducer device of FIG. 1, having a dilator encased within the sheath.

FIG. 4 shows an alternate embodiment of a hub unit which includes a sideport for the infusion or aspiration of fluids.

FIG. 5 shows a seal having a y-shaped slit suitable for use in a hub unit for preventing the backflow of blood and other fluids.

FIGS. 6A and 6B shows further preferred reinforced sheaths of the invention.

DETAILED DESCRIPTION OF THE INVENTION

As discussed above, improved introducer device having flexibility and kink-resistance and preferably includes a reinforcement that encases an underlying sheath. Preferably, the reinforcement member, typically a stainless steel coil or other coil or braided material, has a larger inner diameter than the inner diameter of the underlying sheath. The introducer devices of the invention preferably have a lubricious interior surface that provides for facile insertion of catheters and other devices through the introducer into a patient.

Referring now to **FIGS. 1** and **2**, an introducer device of the present invention is shown to include sheath **10** having a proximal end **14**, a distal end **13** and a longitudinal shaft **12** extending therebetween; a lubricious inner substrate **15** contained within sheath **10**, the lubricious inner substrate **15** having an internal passageway **18**; and a reinforcement member **17** which is capable of surrounding the lubricious inner substrate **15** while being contained within sheath **10**. (In accordance with conventional practice regarding medical devices, "proximal end" designates that end which is closest to the medical personnel manipulating the device, and "distal end" designates the opposite end that is placed within a patient.)

The components of an introducer device of present invention may be made from a number of materials as will be appreciated by those skilled in the art.

Preferably, sheath **10** is comprised of a suitable resin, typically a non-fluorinated resin such as a polyurethane, polyethylene, polyester, nylon, nylon copolymer such as a polyetherblockamide (PEBA), and the like.

In preferred embodiments of the present invention, sheath **10** has dimensions of about 5 to 48 inches in length (distance x in **FIG. 1**) and about 4 French (OD 0.068 inches) to 25 French (OD 0.339 inches) in diameter (distance y in **FIG. 2**). In one preferred construction, the thickness of the sheath wall is about 0.012 inches, although other sheath wall thicknesses also will be suitable.

In preferred embodiments of the present invention, a polymeric layer **16** jackets the outer surface of sheath **10**. In order to achieve variable flexibility of the sheath, the polymeric layer **16** may comprise segments of different materials having different hardnesses. Alternately, the segments may comprise variations of the same or different materials having different hardnesses. This particular feature enables one to readily alter the flexibility of sheath **10** and provides an introducer device that is easy to handle and maneuver, and that is non-traumatic to the vasculature of the patient. Thus, for example, For instance, in one preferred device of the invention, the sheath proximal end has a nylon outer sheath that has a hardness of from about 55 to 75 Shore D, and the distal end of the sheath is formed or polyethylene or a polyurethane and has a hardness of about 35 to 55 Shore D to provide greater flexibility.

As discussed above, it also may be suitable to have a substantially uniform flexibility along the sheath length, particularly in the case of relatively shorter sheaths, e.g. sheaths having an overall length (distance x in **FIG. 1**) of about 6 inches, 5 inches or 4 inches or less.

In particularly preferred embodiments of the present invention, the distal end **13** of sheath **10** is tapered and is more flexible relative to the shaft portion **12** of the sheath. This construction further provides for non-traumatic entry of the device into the vasculature of the patient.

Lubricious inner substrate **15** is adapted to receive an ancillary medical dive, particularly a catheter, needle or dilator **19**, which is specifically illustrated in **FIG. 3**. A dilator is typically used in the placement of sheath introducers to dilate the opening in the tissue, to the sheath. Accordingly, in preferred embodiments of the present invention, the distal end **13** of sheath **10** is tapered to provide a smooth transition

between the distal end **20** of dilator **19** and sheath. This feature minimizes the force required to advance the ancillary medical device (dilator) and sheath assembly through the skin and other tissues.

In preferred embodiments of the present invention, the lubricious inner substrate **15** comprises a fluoropolymer material. Particularly preferred fluoropolymers include polytetrafluoroethylene (PTFE) and fluorinated ethylene-propylene (FEP) polymers.

In an alternate embodiment of the present invention, lubricious inner substrate **15** may be formed from a variety of flexible, non-reactive materials as long as the inside diameter of the substrate is substantially coated with a hydrophilic material. This particular embodiment is generally less preferred, however, due to cost and manufacturing difficulty associated with achieving uniform application of the hydrophilic coating on the inside surface of the substrate.

The length of lubricious inner substrate **15** is tailored in accordance with the dimensions of those of the sheath, and preferably the inner substrate 15 extends the entire length of the sheath, or at least about 95 or 98 percent of the length of the sheath.

Preferred dimensions for internal passageway **18** (diameter z in FIG. 2) defined by lubricious inner substrate **15** range from about 4 French (ID 0.053 inches) to about 24 French (ID 0.315 inches), more preferably from about 5 French (ID 0.066 inches) to about 12 French (ID 0.158 inches).

The lubricious inner substrate **15** provides a smooth surface for easy insertion and transverse movement of the dilator **19**, and subsequently catheters and other ancillary medical devices within sheath **10**. Additionally, use of a smooth inner surface presents a surface which is resistant to blood clot formation.

As discussed above, the device **10** includes reinforcement member **17** that can reduce the possibility of kinking or bending of the sheath during and after entry into the vasculature of the patient. Preferably, reinforcement member **17** is a coiled wire, such as a wound stainless steel braiding or a stainless steel spiral coil. MP-35, a stainless alloy, is a preferred material for the coiled or braided reinforcement. Nitinol

also is a preferred material of construction of the reinforcement member. Nylons and other polymeric materials also can be employed as materials of construction of the reinforcement member.

The pitch of the braiding or coil which form reinforcement member **17** may be varied in order to produce a reinforcement member with non-uniform spacing between the braiding or coil turns. This provides yet another way to vary the flexibility and relative strength of the introducer sheath in order to tailor the introducer device to a particular use, procedure or access site, and the like. For example, suitably the spacing between braiding or coil turns of the reinforcement member will vary from about 0.010 to 0.050 inches over the length of the reinforcement member. The pitch will also preferably vary over defined regions of the reinforcement member. Hence, for example, for a four inch reinforcement member, the first inch of the member proximal end may suitably have a 0.010 spacing between coils, the next two inches may have a spacing of 0.020 between coils and the final inch may have a spacing of 0.025 between coils.

Devices of the invention are highly kink resistant and suitable for use for extended sheath residence times within a patient, e.g. from 1 to 3 hours or more, such as residence times of 6, 9, 12, 18 or even 24 hours or more. Medical procedures that may require such extended sheath residence times include e.g. hemofiltration and dialysis procedures, various cardiovascular procedures and neurological surgical procedures.

Preferably, the composite walls of the introducer device range from about 0.004 inches to about 0.016 inches, more preferably, from about 0.008 inches to about 0.012 inches in diameter.

Referring also to **FIGS. 3, 4** and **5**, in preferred embodiments, introducer devices of the present invention further comprise a hub unit **11** affixed to the proximal end **14** of sheath **10**. The hub unit **11** typically incorporates a valve for hemostasis **21** which may or may not include a sideport **22** for infusion or aspiration of fluids, a standard luer type hub or a custom hub suitable for interfacing with a specific catheter

or other device. A seal **23** positioned within valve **21** prevents backflow of blood and other fluids.

In another aspect of the present invention, the sheath **10** further comprises a radiopaque tracer ring (not shown), preferably positioned at the distal tip of the sheath. Such a configuration permits visualization of the distal end of the sheath within a patient by x-ray or fluoroscopic procedures.

FIG. 6A shows a preferred sheath **30** of the invention having segmented portions of different hardness. The sheath **30** includes tapered distal tip **32** and exterior reinforcement member **34** that preferably terminates before tip **32** as depicted in **FIG. 6A**. As discussed above, the reinforcement suitably may have a variety of configurations, such as a generally flat wire spiral as shown in **FIG. 6A**, or a round wire braid as shown in **FIG. 6B**. Also, other wrapping configurations will be suitable with those materials, e.g., a round wire can be configured as a spiral reinforcement, and the flat wire can be configured as a braided reinforcement.

Sheath **30** also has segments of varying hardness, specifically distal segment **30A** is comparatively the least hard portion of the sheath; a middle sheath segment **30B** that has an intermediate hardness and greater hardness than distal segment **30A**; and a proximal segment **30C** that is the most hard of the depicted three segments.

Sheath **30** also preferably has a lubricous inner liner **36** such as PTFE or other fluoropolymer for the entire sheath length. The sheath also includes proximal hub **38** as discussed above.

As discussed above, the invention also provides methods of manufacturing improved introducer devices having flexibility and kink-resistance and incorporating a lubricious inner substrate.

In preferred embodiments of the present invention, such methods generally include the steps of providing a sheath having a proximal end, a distal end, and a longitudinal shaft; providing a lubricious inner substrate having an internal passageway adapted to receive a dilator, needle, catheter or other medical device, the lubricious inner substrate having a lesser diameter than the sheath; surrounding the lubricious inner substrate with a reinforcement member having a greater diameter

than the lubricious inner substrate (i.e. not a compression fit), but a lesser diameter than the sheath; inserting the lubricious inner substrate surrounded by the reinforcement member into the sheath; and molding the sheath to the lubricious inner substrate and reinforcement member.

In preferred methods of the present invention, molding sheath **10** to lubricious inner substrate **15** and reinforcement member **17** comprises use of a thermal fusion process. The distal portion of the sheath may be tapered if desired. Additional, the distal end of the sheath may be radiused to provide enhanced atraumatic use. The hub unit can then be molded directly onto the proximal end of the sheath.

Hub unit **11** also can be separately formed and then attached, such as by a suitable adhesive. It is also possible to interpose a mounting unit such as a plastic strip between the hub unit and the sheath, although such an arrangement is generally less preferred.

The novel design of the present invention provides an improved introducer device with variable flexibility and kink-resistance. Additionally, the lubricious inner substrate provides for facile insertion of catheters and other ancillary medical devices.

The terms and expressions which have been employed herein are used as terms of description and not of limitation. There is no intent, in the use of such terms and expressions, of excluding any of the equivalents of the features shown and described or portions thereof, but it is recognized that various modifications are possible within the scope of the invention claimed.

What is claimed is:

1. A kink-resistant introducer device comprising:

(a) a sheath having a proximal end, a distal end and a longitudinal shaft;

(b) a lubricious inner substrate contained within the sheath, the lubricious inner substrate having an internal passageway adapted to receive an ancillary medical device; and

(c) a reinforcement member having a greater diameter than the lubricious inner substrate, but a lesser diameter than the sheath such that the reinforcement member is capable of surrounding the lubricious inner substrate and being contained within the sheath.

2. The introducer device of claim 1, wherein the distal end of the sheath is tapered.

3. The introducer device of claim 1, wherein the sheath distal end has been radiused.

4. The introducer device of claim 1, wherein an outer surface of the sheath is substantially covered by a polymeric layer.

5. The introducer device of claim 1, wherein the polymeric layer comprises segments of that differ in hardness.

6. The introducer device of claim 5, wherein the polymeric layer comprises segments that are comprised of differing materials.

7. The introducer device of claim 1, wherein the distal end of the sheath is more flexible relative to the shaft portion of the sheath.

8. The introducer device of claim 1, wherein the lubricious inner substrate comprises a fluoropolymer.

9. The introducer device of claim 1, wherein the device has a substantially uniform flexibility along the device length.

10. The introducer device of claim 9, wherein the device length is about 6 inches or less.

11. The introducer device of claim 1, wherein an inner surface of the lubricious inner substrate is substantially coated with a hydrophilic material.

12. The introducer device of claim 1, wherein the sheath is formed from a polyurethane, polyethylene, polyester, nylon, or nylon copolymer.

13. The introducer device of claim 1, wherein the reinforcement member comprises a metal coil that has differing spacing between coils along the member length.

14. The introducer device of claim 1, wherein the reinforcement member comprises at least one of a wound stainless steel braiding or a stainless steel spiral coil.

15. The introducer device of claim 1, wherein the wall of the composite introducer device is about 0.008 inches to about 0.012 inches in diameter.

16. The introducer device of claim 1, further comprising a radiopaque tracer ring positioned on the sheath and adapted to provide visualization of the distal end of the sheath within a patient by x-ray or fluoroscopic procedures.

17. The introducer device of claim 1, further comprising a hub unit affixed to the proximal end of the sheath.

18. The introducer device of claim 1, wherein an ancillary medical device of a catheter, guide wire or dilator is inserted through the internal passageway of the lubricious inner substrate.

19. A kink-resistant introducer device comprising:

(a) a sheath having a proximal end, a flexible, tapered distal end, and a longitudinal shaft, an outside surface of the sheath being substantially covered by a polymeric layer;

(b) a lubricious inner substrate having an internal passageway adapted to receive an ancillary medical device, the lubricious inner substrate comprising a fluoropolymer and having a lesser diameter than the sheath; and

(c) a reinforcement member comprising at least one of a stainless steel braiding or a stainless steel spiral coil, the reinforcement member having a greater diameter than the lubricious inner substrate, but a lesser diameter than the sheath such that the reinforcement member is capable of surrounding the lubricious inner substrate and being contained within the sheath.

20. The introducer device of claim 19, wherein the reinforcement member comprises has differing spacing between braids or coils of the member along the member length.

21. A method of manufacturing a kink-resistant introducer device comprising:

(a) providing a sheath having a proximal end and a distal end;

(b) providing a lubricious inner substrate having a tubular internal passageway adapted to receive an ancillary medical device, the lubricious inner substrate having a lesser diameter than the sheath;

(c) surrounding the lubricious inner substrate with a reinforcement member having a greater diameter than the lubricious inner substrate, but a lesser diameter than the sheath;

(d) inserting the lubricious inner substrate surrounded by the reinforcement member into the sheath; and

(e) molding the sheath to the lubricious inner substrate and the reinforcement member.

22. The method of claim 21, further comprising affixing a hub unit to the proximal end of the sheath.

23. The method of claim 21, further comprising tapering the distal end of the sheath.

24. The method of claim 21, further comprising radiusing the sheath distal end.

25. The method of claim 21, further comprising applying a polymeric layer of material to an outer surface of the sheath.

26. The method of claim 25, wherein applying the polymeric layer further comprises alternating segments of materials having differing hardness across the polymeric layer.

27. The method of claim 21, wherein providing the lubricious inner substrate further comprises applying a hydrophilic material to an internal surface of the lubricious inner substrate.

28. The method of claim 21, wherein surrounding the lubricious inner substrate with the reinforcement member further comprises sliding at least one of a wound stainless steel braiding or a stainless steel spiral coil over the lubricious inner substrate.

29. The method of claim 21, wherein the reinforcement member has altering pitch or spacing along the member length.

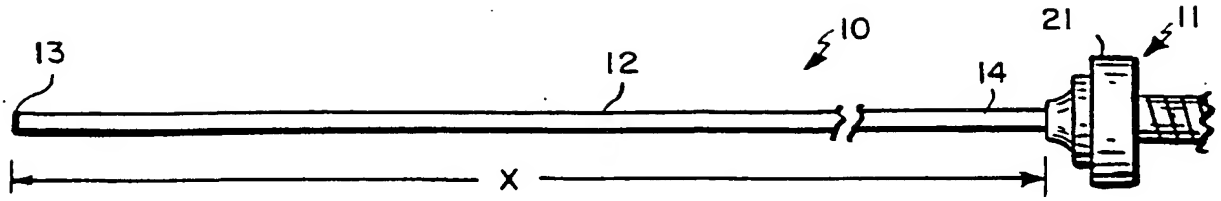

FIG. 1

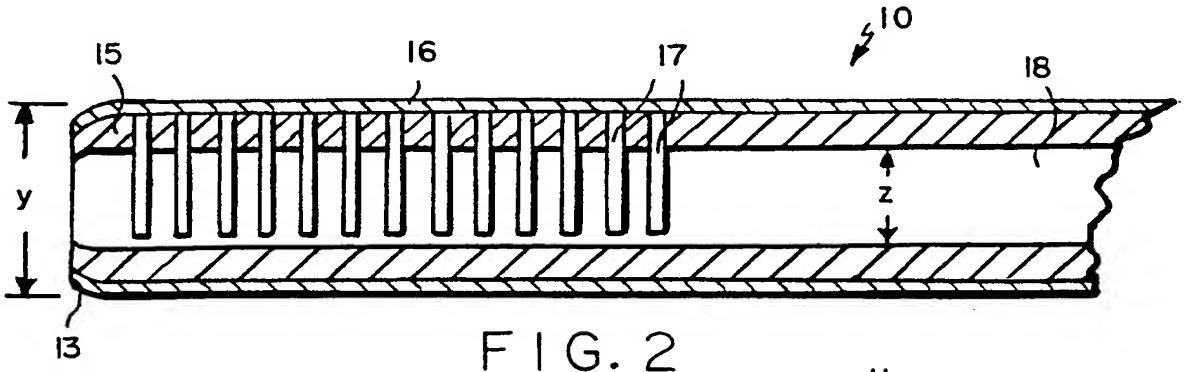

FIG. 2

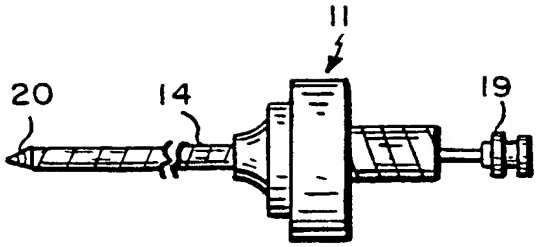

FIG. 3

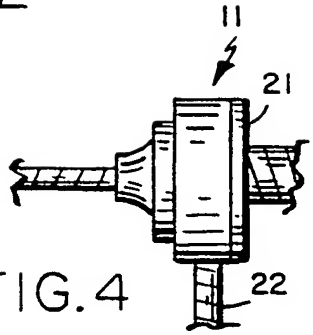

FIG. 4

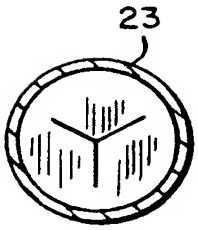

FIG. 5

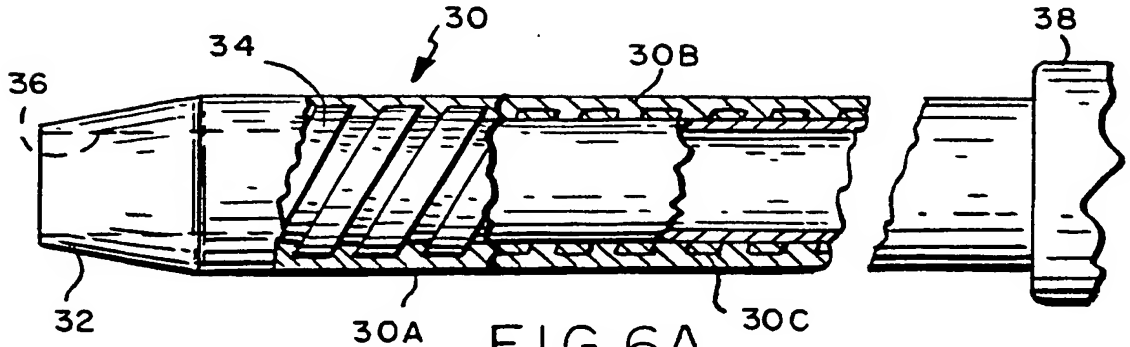

FIG. 6A

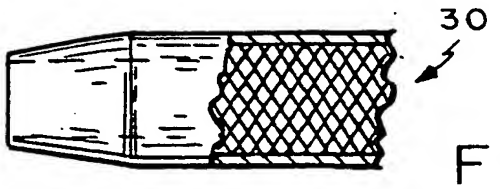

FIG. 6B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/19777

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : B29C 47/02, 39/18, 61/02; B32B 31/26; A61M 25/16, 25/01, 25/098
US CL : 156/86, 143, 144, 245; 604/525, 526, 527; 264/129, 230, 271.1, 279.1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 156/86, 143, 144, 245; 604/525, 526, 527; 264/129, 230, 271.1, 279.1, 319, 342 R; 425/508, 517

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,514,236 A (AVELLANET et al) 07 May 1996 (07.05.1996); column 2, lines 10-27; column 3, lines 12-18; column 3, line 38 - column 4, line 2; column 4, lines 15-28; abstract, claims and figures.	1-3, 7-9, 12, 14, 17, 18, 21-24, 28 --- 1-29
Y, P	US 5,951,539 A (NITA et al) 14 September 1999 (14.09.1999); column 14, lines 37-57; Figure 3D.	4-6, 19, 20, 25, 26
Y	US 4,705,511 A (KOCAK) 10 November 1987 (10.11.1987); column 5, lines 53-64.	11, 27
Y	US 5,695,483 A (SAMSON) 09 December 1997 (09.12.1997); column 4, line 65 - column 5, line 2; column 5, lines 17-23; column 6, lines 22-28; column 7, lines 55-59; abstract and figures.	13, 20, 29
A	US 4,806,182 A (RYDELL et al) 21 February 1989 (21.02.1989).	17, 22
A	US 5,254,107 A (SOLTESZ) 19 October 1993 (19.10.1993).	4-6, 19, 25, 26
A	US 5,380,304 A (PARKER) 10 January 1995 (10.01.1995).	1-29
A	US 5,700,253 A (PARKER) 23 December 1997 (23.12.1997).	1-29
A	US 5,724,989 A (DOBSON) 10 March 1998 (10.03.1998).	16
A	US 5,736,094 A (VAN MUIDEN) 07 April 1998 (07.04.1998).	4-6, 19, 25, 26

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 August 2000 (22.08.2000)	14 NOV 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Jan H. Silbaugh Telephone No. 703-308-0661

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/19777

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A, P	US 6,007,478 A (SIESS et al) 28 December 1999 (28.12.1999).	4-6, 19, 25, 26
A, P	US 6,053,904 A (SCRIBNER et al) 25 April 2000 (25.04.2000).	1-29
A, P	US 6,077,258 A (LANGE et al) 20 June 2000 (20.06.2000).	16

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/19777

Continuation of B. FIELDS SEARCHED Item 3: BRS

search terms: kink$3, introducer, tube, conduit, reforce$4, coil$3, wire, lubricious, lubricant, lubrication, sheath, fusion, thermal, substrate, hub, hardness, taper$3, hydrophilic, braid$3, stainless steel, pitch, spacing, PTFE, polytetrafluoroethylene, FEP, medical